REMARKS

Claims 1-7, 9-12, 14-35 and 47 are pending, and are presented for reconsideration. No amendments have been made to the claims.

The pending claims stand rejected over the Curtet ('726) patent and the Stamm ('670) patent. In the Office Action (page 3), the Examiner acknowledged that the *in vivo* bioavailability data for the claimed fenofibrate formulations was superior to the commercial formulations of Curtet and Stamm. To complete the record, however, the Examiner requested that applicants set forth the actual percentages of fenofibrate and binding cellulose derivative in the test formulations of the invention. Such data is supplied herewith, and described below.

Applicants submit herewith the Second Declaration of George Bobotas, Ph.D., Under 37 CFR § 1.132 ("*Bobotas II*"). That Declaration is supplemental to the first declaration of Dr. Bobotas, dated October 21, 2005 ("*Bobotas I*"). *Bobotas II* shows that the 120 mg, 130 mg and 144 mg formulations described in *Bobotas I* are within the instant claims; and those of the 200 mg and 160 mg TRICOR® formulations are outside the instant claims.

Instant claim 1 requires, among other things, a pharmaceutical composition wherein fenofibrate is present in an amount greater than or equal to 60% by weight, relative to the weight of said pharmaceutical composition, and further wherein a binding cellulose derivative represents between 2 to 15% by weight, relative to the weight of said pharmaceutical composition. Instant claim 21 requires, among other things, a pharmaceutical composition wherein the fenofibrate and the binding cellulose derivative are present in a mass ratio of between 5/1 and 15/1.

130 mg ANTARA® capsules v. 200 mg TRICOR® capsules (Curtet ('726) patent):

Bobotas II shows that the formulation of the 200 mg TRICOR® capsules of the Curtet ('726) patent is 58% fenofibrate by weight, relative to the weight of the formulation. *Bobotas II*, ¶ 7. Thus, the formulation of the 200 mg TRICOR® fenofibrate capsules of the Curtet ('726) patent are outside the instant claims.[1]

The 130 mg ANTARA® formulation of the invention is 64% fenofibrate by weight relative to the weight of the granules, and 12% by weight binding cellulose derivative, relative to the weight of the granules. *Bobotas II*, ¶ 4. Thus, the 130 mg ANTARA® formulation is within the instant claims.

As was shown in *Bobotas I*, the 130 mg ANTARA® formulation of the instant claims yields surprising and unexpected results as compared to the 200 mg TRICOR® formulation of the Curtet ('726) patent. The 130 mg ANTARA® capsules produced 25.5% greater bioavailability per mg fenofibrate than that of the 200 mg TRICOR® fenofibrate capsules following consumption of a therapeutic lifestyle change (TLC) meal (*Bobotas I,* ¶ 8 and Table 2); and it produced 37.3% greater bioavailability per mg fenofibrate at steady state (*Bobotas I*, ¶ 12 and Table 4).

[1] Applicants are unable to determine the weight percent, if any, of binder in the 200 mg TRICOR® formulation. The Curtet ('726) patent does not describe any of the ingredients used in that formulation as "binders." *Bobotas II*, ¶ 6. Nonetheless, the 200 mg TRICOR® capsule formulation is outside the scope of instant claim 1 for at least the following reasons: 1) it has less than 60% by weight fenofibrate relative to the weight of formulation; and 2) it does not use a neutral microgranule.

120 mg and 144 mg capsules v. 160 mg TRICOR® tablets (Stamm ('670) patent):

Bobotas II shows that the 160 mg TRICOR® fenofibrate tablets of the Stamm ('670) patent are 23% fenofibrate by weight, relative to the weight of the tablet. *Bobotas II*, ¶ 9. Thus, the 160 mg TRICOR® fenofibrate tablets of the Stamm ('670) patent are outside the instant claims.[2]

The 120 mg and the 144 mg formulations of the instant claims are 64% by weight fenofibrate relative to the weight of the granules, and 12% by weight binding cellulose derivative, relative to the weight of the granules. *Bobotas II,* ¶ 4. Thus, as with the 130 mg ANTARA® formulation, the 120 mg and the 144 mg formulations are within the instant claims.

Applicants have previously shown that in comparison to the 160 mg TRICOR® tablets of the Stamm ('670) patent, the 120 mg and 144 mg formulations of the instant claims have 20% and 14.7% greater bioavailability per mg fenofibrate, respectively. *Bobotas I,* ¶ 16 and Table 6. Accordingly, the formulations of the instant claims produce surprising and unexpected results in enhanced bioavailability per mg fenofibrate.

Applicants respectfully submit that the record is now complete and that the Examiner should give full weight to the comparative evidence provided in *Bobotas I.*

In view of the foregoing amendments and remarks, applicants respectfully request reconsideration and withdrawal of all outstanding rejections. Applicants

[2] Again, Applicants are unable to determine the weight ratio of any binder in the 160 mg TRICOR® tablet. Nonetheless, the 160 mg TRICOR® formulation is outside the scope of instant claim 1 if only because it has less than 60% by weight fenofibrate relative to the weight of the pharmaceutical composition. In addition, the Stamm ('670) patent requires formulations having at least 20% hydrophilic polymer (Stamm at col. 3, lines 13-23, and claim 1). Thus, it would appear that the 160 mg TRICOR® formulation is outside the scope of instant claim 1 because it does not have between 2 to 15% by weight binding cellulose derivative relative to the weight of the pharmaceutical composition.

submit that the claims are now in condition for allowance, and respectfully request formal notification to that effect. If, however, the Examiner perceives any impediments to such a notice of allowability, whether substantive or formal, the Examiner is encouraged to call Applicants' attorney at the number provided below. Such informal communication will expedite examination and disposition of this case.

Respectfully submitted,

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